K031711

1 of 2

AMERICAN BANTEX CORPORATION
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Tracy S. Best, Regulatory Affairs Consultant
Preparation Date: May 27, 2003

DEC 1 8 2003

Summary of Safety and Effectiveness for the:

Trade Name: Tango Powered Wheelchair, Models BP1 & BP1A

Common Name: Power chair

Classification Name: Powered Wheelchair ITI, Class II, 21 CFR 890.3860

Legally Marketed Predicate Devices for Substantial Equivalence:

* Explorer Powered Wheelchair by EVERMED Corporation, and cleared for marketing under 510(k) K023485.

* CHOICE Powered Wheelchair by American Medical Technologies, Inc. and cleared for marketing under 510(k) K963808.

Rationale for SE:

The Tango powered wheelchair is substantially equivalent in safety, efficacy, technology and intended use to its predicate devices. The construction of the tubular frame, battery operation, two motors and automatic braking systems are all similar. Battery chargers and the instructions for their use are supplied with both chairs. Travel range, speed settings and maximum speed are similar, although they have minor variations on these parameters.

Description of Submitted Device:

The Tango Powered Wheelchair is an indoor/outdoor powered wheelchair that is battery operated. The two models are identical, except the frame. The BP1 has a steel frame and the BP1A has an aluminum frame. The available options include a curb climber, additional joystick controller for an attendant, and the ability to disengage the wheel motor gearbox so that an attendant may use the chair as a free-wheel device. The automatic braking feature engages within one-half second when the controller is released. Both models can be disassembled for easy transportation and reassembly and use.

Intended Use of the Tango Powered Wheelchairs:

The Tango Powered Wheelchair (Model BP1 & BP1A) is indicated to provide enhanced mobility to physically challenged persons/patients who are limited to a sitting position for various medical reasons.

Some, but not all of the specific indications for use for powered wheelchairs are: paraplegia, quadriplegia, muscular dystrophy, muscular sclerosis, lower limb amputation, neurologic or other muscular diseases which render limbs too weak or unstable for normal use or activity.

Technological Characteristics and Substantial Equivalence:

The Explorer Powered Wheelchair is an indoor/outdoor powered wheelchair that is battery operated. The product has a metal frame with four wheels, an adjustable seat with armrests, and a controller attached to one armrest. The controller allows the rider to control the movement of the chair. The chair can be disassembled for transport and is provided with a battery charger. These features are all similar to the Tango model wheel chairs.

The Choice Powered Wheelchair is available with a 16 or 18 inch wide wheel base and with seat widths of 14 to 20 inches and seat depths of 14 to 24 inches. The wheelbase and adjustable seats are two features that differ from the Tango. The Choice battery operated wheelchair is constructed of welded fabricated steel. The Choice wheelchair has two motors to drive the rear wheels powered by two 12 volt batteries wired in series to provide 24 volts DC. A joystick controller or optional "sip-n-puff" controller controls the functions of the Choice wheelchair. The Tango does not offer the "sip-n-puff" option because our wheelchair does not have software programming and therefore has fewer equivalent features than the Explorer wheelchair.

Conclusion:

The Tango Powered Wheelchair, Models BP1 and BP1A are similar in design, construction, safety, efficacy, controller, braking systems and voltage use to other currently legally marketed devices for the same intended uses. Compliance with voluntary standards and guidance documents published by international agencies, as well as by the Food and Drug Administration. The Tango as well as its comparative equivalent devices has passed EMC testing for Electromagnetic Immunity. We feel that although there are minor variations, the device submitted is substantially equivalent to already legally marketed devices on the market.

Testing Conducted:

Tests listed in the *Guidance Document for the Preparation of Premarket Notification Applications for Mechanical and Powered Wheelchairs, and Motorized Three Wheeled Vehicles*, July 1995, were conducted as well as other international compliance/conformity tests and are identified within the submission.

Performance Testing:

Comparative performance testing and clinical evaluations were not conducted nor submitted as part of this 510(k).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 8 2003

American Bantex Corporation
c/o Tracy S. Best
994 North Main Street
Bountiful, Utah 84010

Re: K031711
Trade/Device Name: Tango, Model BP1
Regulation Number: 890.3860
Regulation Name: Wheelchair, powered
Regulatory Class: II
Product Codes: ITI
Dated: December 1, 2003
Received: December 2, 2003

Dear: Mr. Best:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):_____

Device Name: Tango, Models, BP1 and BP1A

Indications for Use:

The Tango Series Powered Wheelchairs are indicated to provide enhanced mobility to physically challenged persons/patients who are limited to a sitting position for various medical reasons.

Some, but not all of the specific indications for use for powered wheelchairs are: paraplegia, muscular sclerosis, lower limb amputation, neurologic or other muscular diseases which render lower-limbs too weak or unstable for normal use or activity.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Mark N. Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031711

Prescription Use (Per 21 CFR 801.109) OR Over-The-Counter Use ✓